NO. 27

IN THE

Supreme Court of the United States

OCTOBER TERM, 1958

MARION B. FOLSOM, SECRETARY OF HEALTH, EDUCATION AND WELFARE,

Petitioner,

v.

FLORIDA CITRUS EXCHANGE, FRANK R. SCHELL, ET AL.

ON WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE FIFTH CIRCUIT

BRIEF FOR RESPONDENTS OTHER THAN FRANK R. SCHELL

J. HARDIN PETERSON
P. O. Box 111
Lakeland, Florida

J. HARDIN PETERSON, Jr.
Of Counsel

Attorney for Respondents
other than Frank R. Schell

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vs.

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BRIEF OF RESPONDENTS OTHER THAN FRANK R. SCHELL

QUESTIONS PRESENTED

The questions as stated by Petitioner fail to take into consideration the fact that in the opinion of the Court wide discretion was still allowed in the Secretary to determine the tolerances and to determine if the other requisites existed and to make further investigation and conduct hearings. (R. 183, 2nd paragraph; R. 187, last paragraph)

We submit our view that the questions to be decided on the review could be simply stated as follows:

1. Did the Court of Appeals for the Fifth Circuit commit error in holding that the word "harmless" must be construed in a relative sense and not in an absolute sense and in holding that the Secretary erred in taking FD&C Red No. 32 off of the certified list for use in coloring oranges not for processing and meeting the proper maturity standards when in the manner and quantity as used in the coloring of oranges same was harmless and where there is no showing of likelihood of injury to human beings at the ordinary,

normal levels of use, and when this color had been on the certified list for nearly twenty years and when nothing was learned in the new hearings that was not known at the time of the original certification.

2. Did the Court of Appeals for the Fifth Circuit err when it held that the Secretary has power to certify for a limited use and/or to provide a tolerance and that he erred in entering the order when he construed the Federal Food, Drug and Cosmetic Act as not giving him such powers?

The Court in its opinion (R. 178) states the question as follows:

> "The decision we are to make is whether the Secretary of Health, Education and Welfare is required or permitted to determine if there is a minimum quantity of the coal-tar color designated as FD&C Red No. 32 which can be used in adding color to the skins of mature oranges without danger of impairing the health of those who consume such oranges; and if so required or permitted, and if it be determined that there is such minimum, should the Secretary list and certify such color for such use."

STATUTE INVOLVED

In addition to the portion of the statute set forth in the Petitioner's Brief, we set forth herein Section 402(c) as it appears in the Federal Food, Drug and Cosmetic Act at the Time of the Secretary's order:

> "Sec. 402(c) If it bears or contains a coal-tar color other than one from a batch that has been certified in accordance with regulations as provided by Section 346 of this title: PROVIDED, That this paragraph shall not apply to citrus fruit bearing or containing a coal-tar color if application for listing of such color has been

made under this chapter and such application has not been acted upon by the Secretary if such color was commonly used prior to the enactment of this chapter for the purpose of coloring citrus fruit;"

This was subsequently amended by Public Law 672, 84th Congress, 2nd Session, taking effect July 9, 1956 as shown (c) page 3 of Petitioner's Brief.

A portion of Paragraph 371 of 21 U.S.C.A. is pertinent:
(e) ... The Secretary shall base his order only on substantial evidence of record at the hearing and shall set forth as part of the order detailed findings of fact on which the order is based ...."

As is also Section 7 of the Administrative Procedure Act:
"In hearings which Section 1003 or 1004 requires to be conducted pursuant to this section ...
"...

"(c) Except as statutes otherwise provide the proponent of a rule or order shall have the burden of proof ..." 5 U.S.C. 1006.

STATEMENT

The Secretary of Health, Education and Welfare had hearings and issued an order under date of November 10, 1955 removing coal-tar color FD&C Orange No. 1, Orange No. 2 and Red No. 32 from the approved list of harmless colors for the unrestricted use in food, drugs and cosmetics (R. 158). The Certified Color Industry Committee took an appeal to the Second Circuit as to the entire order and the Second Circuit refused to reverse the Secretary. Its opinion appears in 263 Fed. 2d 966.

The Florida Citrus Exchange and a number of growers and packers in the State of Florida and in the State of

Texas took an appeal to the Court of Appeals of the Fifth Circuit in so far as the order affected the use of FD&C Red No. 32 as used in the coloring of mature oranges meeting certain other specifications. Frank Schell also took the review proceedings to the Fifth Circuit. The Fifth Circuit rendered the decision which Petitioner is seeking to review by certiorari. These two cases were briefed separately but argued together and one opinion rendered. (R. 168-191; 246 Fed. 850) Petition for rehearing en banc was filed by the Secretary and denied.

A. The Secretary's Order:

Red 32 was placed on the approved list in 1939 after a public hearing at which its harmlessness was established. The color which was certified as Red 32 had been used for the coloring of oranges prior to the passage of the Federal Food, Drug and Cosmetic Act in 1938. While the Department of Health, Education and Welfare did initiate new studies yet the tests and studies were not to determine whether the color was harmful at the levels as actually used under normal conditions of use and the tests were not made at levels of ordinary conditions of use and the amounts of the color fed to test animals were far in excess of that used in the coloring of oranges, (R. 209-210-211) and the Secretary found the evidence inadequate to support the findings as to the amount of color likely to be ingested by man from his foods, drugs and cosmetics (R. 164, Finding 10). The amount of dye in parts per million in the coloring of oranges is shown as Exhibit 8 (R. 225 and 259) and an analysis of this testimony appears on pages 112, 113, 114 and 115 of the Record. At the levels fed a man would have to eat from 2250 oranges to 45000 oranges per day (R. 113) before he would get enough of the color to show ill effects from the color and could drink 5000 gallons of juice per day without any ill effects attributable to the color. Nothing new was

developed in these hearings that was not known at the time the color was certified in 1939.

Reference is made to possible carcinogenicity as causing investigation. The Commissioner of U. S. Foods & Drug Administration now states no evidence to that effect and action has been misinterpreted.

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The orange is one of the very few fruits which has blossoms, small fruit and fully mature fruit on the tree at the same time; in the Fall until the cool days come a fully ripe and mature fruit may be green on the outside, when cool weather comes the late variety of orange may have a rich color on the outside and not be fully mature inside. Later in the Spring when the chlorophyll (green color) rises in the tree it goes into the leaves and new fruit and likewise goes into the mature and ripe fruit "regreening it", causing it to be green on the outside although it is fully mature and by reason of this it is impossible to sell unless it is colored. Only oranges meeting high standards of maturity may be colored. The use of color does not involve any element of deception as the oranges are marked "color added". Section 402 of the Act specifically prohibits the use of any color to conceal damage or inferiority in a food product. FD&C Red No. 32 was the only color used in coloring oranges and was being sold for such purpose only. (R. 227) The coloring of mature oranges has long been recognized by the Industry, the Department of Agriculture and the Congress as a necessary trade practice and an economic necessity, as will be shown with detailed citations in a subsequent section of this brief. The taking of the colors off of the approved list was not because of any harm or claimed harm as used in the coloring of oranges, the Secretary stating:

"While the scientific evidence so far available does not establish what the lowest safe dosage would be to test animals, neither does it establish a likelihood of injury to man from the use of this color on the exterior of oranges at the levels of use involved.

"...

"The evidence so far available does not establish a likelihood of injury to man from the minute amount likely to find its way into the human diet from the consumption of such colored oranges at the level of use involved." (Report of Secretary of Health, Education and Welfare, February 13, 1956—House Hearings on HR 7732, 84th Congress 2d Sess., p. 3)

3. The Petitions to reopen were overruled on the assumption by the Secretary that he had no right to continue the certification of colors if they were harmful if fed at high levels to test animals, even though the colors were not harmful when used in normal use in limited quantities, and that he had no authority to limit for particular use or to limit the quantities used. (R. 164, Finding 11; R. 165, Finding 12). It is out position that it was this erroneous construction of the law by the Secretary which caused the order to be entered.

Reference is made on page 7 of Petitioner's Brief to the statement of the Florida Citrus Commission. However, the Director plainly stated "it is our understanding from the notice of hearing in the Federal Register that the merits of coloring oranges are not involved in the hearing". (R. 224) Certainly he couldn't assume that the Food and Drug Administration would, on the same type of testimony, reach a different decision than it had in 1939.

B. Temporary Legislation:

1. The introduction of H. R. 7732 was after the Secre-

tary's tentative order had been entered, but before the decision of the Fifth Circuit, and before the Fifth Circuit had granted a stay, but it was not passed until after the Secretary's final order. The coloring of oranges was an economic necessity and had long been encouraged by the Department of Agriculture and, not knowing whether the Fifth Circuit would grant a stay, efforts were made through legislation to continue the use, but as will hereinafter be shown in the argument, it was not intended to limit its use in the event the Court found under the Act that certification could be continued. The words "less toxic" on page 10 of the Secretary's Brief are his own conclusion and are not in the bill itself. The hearings show that the report of the Department had not come in until the day the hearings began, and, when informed of the statement of the Department, the proponents of the legislation agreed to the amendment. The bill, as introduced, appears on page 1 of the hearings before the House Committee and uses the words "more acceptable on the basis of standards set up by the Secretary", etc. (Hearings, House Committee on Interstate and Foreign Commerce on H. R. 7732, 84th Congress, 2d Sess., pp. 2-3) This legislation allowed the use of FD&C Red No. 32 for the coloring of oranges meeting certain standards until March 1, 1959, unless prior thereto another coal-tar color suitable for coloring oranges is listed under Section 406. It is made clear that the use could be continued for such purposes if the Court so determined. The Senate Report concludes with the following words:

> "Inasmuch as the judicial proceeding referred to above have not as yet been concluded, the committee wants to make it clear that if it is finally judicially determined that the Secretary of the Department of Health, Education, and Welfare already has the power to certify F.D.&C. Red No. 32 for use on the exterior of oranges, the instant legislation is not intended to limit or modify that power."

S. Rep. 2391, 84th Congress, 2d Sess., p-3

The primary purpose was to grant a stay for at least three years. Of course, if the Court determined that under the construction of the Act it could certify then the Congress made it clear in its report that it did not intend to limit the Court's decision.

Reference is made in the Petitioner's Brief to Florida and Texas orange growers. Under the Special Act and the decision all users of F-D&C Red No. 32, including the users in California and Arizona, get the benefit. The Record shows the interest of certain California and Arizona growers. (R. 116)

LITIGATION:

The sequence of the litigation is given in the Petitioner's Brief. The two cases before the Court were consolidated. Separate briefs were filed but the cases were heard together. The U. S. Court of Appeals for the Fifth Circuit reversed the Secretary's Order and concluded its opinion as follows:

"After a hearing in 1939 Red 32 was found to be harmless and suitable for use in foods, drugs and cosmetics. The situation as presented on this review was briefly and accurately characterized in a letter from the Commissioner of Food and Drugs to Florida Senators and Congressmen written February 8, 1955. In speaking of Red 32 the Commissioner said:

'Recent investigations show that these colors when fed in substantial amounts, show evidence of toxicity. There is, however, no evidence that, in the amounts used, and in the manner of use, in the coloring of citrus fruit, the product so colored is not safe for human consumption.'

"Unless there is evidence that, in the amounts used, and in the manner of use, oranges colored with Red 32 are unsafe for human consumption, the 1939 finding should not be supplanted by a contrary ruling by which such use is prohibited. It may be parenthetically observed that 'unsafe' is the yardstick for determining tolerances under Section 406(a). A determination may be made by the Secretary on his own initiative or upon the petition of any interested person as to whether coloring is required and, if so, as to whether Red 32 is a harmless coal-tar color for use in coloring oranges and to fix the tolerances, if any, as may be proper for such use.

....

"The order promulgated by Marion B. Folsom, Secretary of Health, Education and Welfare, on November 10, 1955, published in the Federal Register on November 16, 1955, (20 F. R. 8492) will be set aside in so far as said order removes the coal-tar color FD&C Red No. 32 from the list of colors which may be certified for use in coloring the skin of oranges meeting minimum maturity standards prescribed in the State of Florida and Texas; provided, that nothing herein or in the judgment of this Court entered pursuant hereto shall restore said coal-tar color to the list of colors which may be certified for unrestricted use in food, drugs and cosmetics but shall operate to authorize the certification of batches of said color conforming to the specifications for the color appearing at 21 C.F.R. 135.3 (1949 ed.) for the purpose of coloring the skin of mature oranges only; provided further, that the Secretary shall be required to certify only sufficient batches of FD&C Red No. 32 as may be necessary to color the skin of mature oranges from time to time; provided further, that the certificates issued for batches of FD&C Red No. 32 may be limited by their certificate for use in coloring mature

oranges only; and provided further, that nothing herein or in the judgment of this Court entered pursuant hereto shall be deemed to restrict the Secretary from making further investigations and conducting hearings for a determination of (fol. 310) whether the use of Red is required in the production of oranges and to determine the tolerances, if any, that are safe and harmless, as harmless is herein construed and defined."

The Court pointed out in its opinion the difference between this case and the one in the Second Circuit, stating that the identical issues were not presented and a different principle is involved. In the Second Circuit case three coal-tar colors were involved and the uses were all-inclusive (R. 176). The Second Circuit case also had shown that the two cases were different and the Fifth Circuit quoted from the Second Circuit to this effect. (R. 176) In the cases in the Fifth Circuit only one color and one commodity were involved. In the Certified Color Industry case the whole field of foods was involved and there was not testimony as to the amount of color used. In our cases there was testimony as to the amount of color used on oranges. The decision held the words "harm", "harmful" and "harmless" are terms of relation (R. 180) and also held that the Secretary could grant tolerances or certify for a limited purpose and pointed out that the Secretary had on previous occasions so construed the Act. (R. 184) We consider the Fifth Circuit opinion well reasoned and that it show a clear conception of the evidence as well as the law and recognized the rule laid down in U. S. vs. Lexington Mill and Elevator Co., 232 U. S. 399, 34 S. Ct. 337, 58 L. Ed. 658.

SUMMARY OF ARGUMENT

I

Red 32 is not poisonous or harmful as used in the coloring of Oranges.

A. The evidence referred to by Petitioner was based on tests having no relation to the amounts in normal uses in food, or the amounts as used in the coloring of oranges.

B. The statute, read as a whole and in the light of its legislative and administrative history, intended that the uses and quantities of the coal-tar colors be taken in consideration in listing and certifying for use.

A. Petitioner takes the position that there must be zero toxicity. By this test nothing could be certified. The articles of everyday food, and water itself, can be harmful if taken in excessive quantities, and other things considered harmful may, when taken in small quantities, be beneficial.

The tests were made at levels far in excess of the normal levels of use generally and far in excess of the use in coloring oranges. The Petitioner's own witness stated (R. 216-217) that the amount of dye had to be considered in determining whether it is harmless. This was ignored in the findings. The Secretary admitted that the amount likely to be ingested by man was minute, that he could not say that its continued use on oranges would pose a hazard to the public health and there is no present evidence of injury to man.

The summary of evidence shows that a man could drink 5000 gallons of juice per day from color added oranges without injury, and that the feeding of rats was at a rate

7550 times as much color as a man would get if he ate six oranges per day, peel and all. Publications by eminent scientists in this field quoted in the argument point out that the use, quantities and circumstances have to be considered in determining whether a substance is harmful.

B.

1. The legislative history and the administrative background, as well as the Act as a whole, show that it was never intended by the Act to prohibit the listing of coal-tar colors when they were harmless in the manner and quantity as used. The word "harmless" was used in regulations under the previous regulations and yet substances, including coal-tar colors, were certified when it was known that at high levels such substances could be harmful. The hearings on the Food, Drug and Cosmetic Act showed that it is extremely difficult to acquire absolute purety, that it was intended to give legislative sanction to administrative practice and continue the system of certification, and to insure the continued availability of colors. At the time of passage of the Act Congress knew that no coal-tar color could be used for all purposes or in all amounts. In 1939 shortly after passage of the Act, Dr. Calvary, an eminent pharmacologist, at that time Chief of the Division of Pharmacology of the Food and Drug Administration, testifying at the certification hearings on FD&C Red No. 32, showed clearly that the Department then considered both the use and quantity of coal-tar colors in determining whether they were harmful. Nothing new was developed in the hearings on which FD&C Red 32 was decertified that was not developed at the original hearings on which it was certified. The United States Supreme Court decision and the quotation therein from the statement of the Chairman of the House Committee handling the legislation at the time of passage of

the earlier Food and Drug Act plainly states: "Everything that contains poison is not poisonous. It depends on the quantity and combination." All evidence shows that the color is not harmful as used on Oranges. It cannot be used to conceal inferiority as a seperate section of the Act prevents this and the State Laws require a higher standard of maturity before an orange is allowed to be colored.

2. The Food and Drug Administration took the position that it could not certify for a limited use or to prescribed tolerances for coal-tar colors, yet it is shown that it had certified coal-tar colors for limited uses previously and had also certified colors that were harmful if fed at high levels. The Congressional hearings showed time and time again that the Chairman of the Senate Committee and the sponsoring witness appearing for the Food and Drug Administration recognized that the Act contemplated that the Secretary had the right to provide tolerances and to certify for limited purposes. In Section 406 the Secretary is directed to list colors which are harmless for use in food. In Section 504 he is directed to provide for the listing of colors that are harmless for use in drugs and in Section 604 he is directed to provide for the listing of colors which are harmless for use in cosmetics and could be certified for a limited use.

II

There is a clear showing that there is necessity for the use of this color in the production of oranges.

A number of reports of the Department of Agriculture quoted in this brief show that early oranges may become fully mature while still green on the outside while late oranges may be a full rich color and not be mature, and

that after maturity may regreen when the chlorophyll comes into the tree and enters the oranges again in the Spring.

This is the only color now certified for use on oranges and it is not used for any other purpose. It cannot be used to conceal defects or to defraud because State laws require a fuller maturity before coloring is allowed, and specifically prohibits the use of color for deceiving or defrauding.

The Secretary takes the position that added poisonous and deleterious substances were banned without regard to whether the added substances might or might not render the treated food injurious. This is contrary to the entire concept of the Food, Drug and Cosmetic Act. The two purposes of this Act were to protect the public health and to prevent deceit. Neither of these purposes is served by denying the use of a color harmless as used and in such manner that it would be impossible for a human being to ingest enough color from eating oranges to reach any level at which he would be harmed. The Department of Agriculture and the Congress of the United States have approved the use of the coloring and have declared it an economic necessity in the coloring of oranges. The Secretary takes the position that this decision will have far reaching consequences beyond the question of Red 32 for oranges. This statement of the Secretary was made prior to the passage of Public Law 85-929 and this decision will have no effect upon the other food additives. Congress has now spoken again. If this be a reversal of the national food policy which has been followed for years, Congress has itself entered into such reversal, but the policy on oranges is the policy that has been followed for years. Red 32 has been in use for more than 20 years.

III

The Court below did not make its own findings that coloring of oranges is required for production and casting on the secretary the burden to show that safe tolerances can be established. The Court followed the clearly established facts and the law in existence at the time.

The Court of Appeals did not presume the safety of Red 32. It took the Secretary and Food and Drug Administration's own interpretation. The record before the Court showed that it was harmless as used. There was no showing that would justify its being taken from the certified list after 20 years of use. The evidence on which it was taken from the list was substantially the same evidence as that on which it was certified.

In this case the Secretary was the proponent. The Secretary was seeking to take from the certified list a color that had been used for the coloring of oranges for more than 20 years, that had been certified by the Secretary, that had been in use at the time of the passage of the Food and Drug Act. The Administrative Procedure Act, which is applicable to the Secretary, hereinbefore quoted, provides that the proponent of a rule of order shall have the burden of proof. The Food, Drug and Cosmetic Act provided he should base his order only on substantial evidence of record at the hearing. There was a lack of substantial evidence.

IV

Recently enacted legislation

In the closing days of the second session of the 85th Congress the food additive bill, H. R. 13254, which became Public Law 85-929, (72 Stat 1784) was passed. This puts

at rest many of the questions raised by the Secretary, which is applicable to various phases of the argument. This specifically authorizes tolerances and provides a method of establishing safety and the formula therein takes into consideration the proposed use and probable consumption.

This Act, covering the broad field of food additives, puts at rest the fear of the Secretary as to the effect of this decision on sweeteners, oleomargarine and other foods; it puts at rest the fear that this decision will change the food policy because this policy is now established by Congress with the duty of the Secretary to establish tolerances. The reports accompanying this legislation provided that the concept of safety is where the substances are hazardous to health and also takes into consideration the probable consumption of the additive. Certainly, it is not reasonable to assume that that which is applied to the outside of the orange, where any amount likely to be ingested is minute, must be zero toxicity and should be construed by the Secretary as not harmless, when at the same time a greater quantity of material known to be toxic is allowed by tolerance or determination of safety to be placed in food intended for use.

ARGUMENT

I

RED 32 IS NOT POISONOUS OR HARMFUL AS USED IN THE COLORING OF ORANGES

A. The evidence referred to by Petitioner was based on tests having no relation to the amounts in normal uses in food, or the amounts as used in the coloring of oranges.

Petitioner's statements in brief are based on the erroneous construction of the words "harmless" and "suitable

for use," the Secretary taking the position there must be zero toxicity. Therefore the tests were made at levels far greater than normal use.

The statutory language, "harmless and suitable for use" must be construed in the light of the intention of the Act and the testimony and orders in existence as shown by the legislative history. It should not be given an absurd and unreasonable construction. No substance can be said to be "harmless and suitable for use" in the abstract. Strychnine and arsenic, for example, which are highly toxic in relatively low concentrations, are completely harmless and indeed beneficial in the treatment of human diseases when used in the proper quantities under appropriate conditions. On the other hand vinegar and table salt, which are normally not thought of as toxic, can produce illness and death if consumed in excessive quantities. Indeed, the Petitioner's own expert witness, upon whose testimony the orders were based, testified in the hearings in the present proceedings:

"Were you using the term 'harmless' then in the absolute sense that each of the colors were capable of producing harm? A. That is correct.

"Q. In that sense, then, is not common salt capable of producing harm? A. Well, I believe in the case of common salt you have to take into consideration the fact that it is essential to live, so that since you can't get along without some salt, I don't think you could ordinarily consider salt harmful. (R. 212).

"Question. Nevertheless, if you took salt in a quantity of two or three ounces, you may get some bad results from salt? A. There would be some adverse effects from two or three ounces of salt, yes. (R. 212-213)

"...

"Q. Dr. Vos, aren't the amount and method of proposed use of a material necessary data for deciding whether the material is harmless for the use intended? "The Witness: I would say, yes." (R. 216)

"The Witness: Yes, The amount of the dye, of the color, has to be considered in determining whether or not it is harmless." (R. 216)

Again, Dr. Vos, Petitioner's expert witness, testified:

"Well then, these levels were not specifically related to the levels of these colors as actually used under normal conditions of use. No, that was not a part of this.

"Q. Have you any evidence at such levels where the capacity for producing harmful effects was tested at levels of ordinary conditions of use? A. I have very little information on the matter of what the customary levels of use are." (R. 211)

"Q. Dr. Vos, then, you have no evidence as to the capability of producing harmful effects of any of these colors at the level of ordinary use under normal conditions of use, I should say?

Dr. Vos: Without having more thorough information on the actual level of ordinary use, I would hesitate to answer that question.

"Q. Well, you have no evidence at levels other than the levels appearing in the exhibits?

A. That appear in the exhibit, that is correct." (R. 211) "Yes, the amount of dye, of the color has to be considered in determining whether or not it is harmless." (R. 216)

"The Witness: I think it is appropriate the method of use should be taken into consideration. The dyes in question are at present being certified for use in foods, drugs, and cosmetics, and the data which we presented in these exhibits have shown that they are not harmless for use in all of those products. As I have pointed out, we have no data as to whether they are or are not harmless for external application." (R. 217)

From a technical viewpoint a distinguished food chemist sums matters up with the following statement:

"There is no foundation in toxicology for regarding all substances as either poisonous or deleterious, on the one hand, or safe or harmless, on the other. The optical physicist has his absolute white and absolute black, but there are no absolutes for the toxicologist. 'Toxicity' depends on species, age, weight, sex, dosage, route of administration, physiological or pathological state, and manifold other factors comprising 'experimental conditions'. Translation of toxicity data into terms of real or potential effect under any given set of circumstances, as for example, the determination of hazard to any particular segment of the population or to the public health generally, involves considerations that go far beyond toxicity effects in laboratory animals." [1]

Since the Secretary's decision was made there has been Completed a study by the Department of National Health and Welfare, Canada, which confirms a level of no effect in FD&C Red No. 32. A pertinent portion of the report reads as follows:

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1. Oser, CAN A POISON EXIST IN A VACUUM? A Discussion of Section 406(a), 8 Food, Drug, Cosmetic Law Journal, 693, 696 (1953).

"F.D. & C. Orange No. 2, F.D.&C. Red No. 32, and F.D. & C. Green No. 2 in concentrations of 0.03% in the diet did not affect growth, food consumption, or food efficiency in either male or female rats."

CHRONIC TOXICITY STUDIES ON FOOD COLORS By M. G. Allmark, H. C. Grice, and W. A. Mannell. Food & Drug Laboratories, Dept. of National Health and Welfare, Canada, Journal of Pharmacy & Pharmacology Vol. 8; pages 417-425, June 1956

This is far in excess of the four parts per million used on the peel in coloring oranges. Certainly when a dye is used below a no-effect level it is harmless both in fact and in law.

The best scientific opinion agrees with this position; the Ad Hoc Advisory Committee of the National Academy of Sciences in its report of June '56 pointed out that the certification of a compound as "harmless and suitable for use" in food, etc, is unrealistic unless the level of use is specified, and that under the rigid interpretation of this directive many components of ordinary diet could not be certified.

The Report of the Ad Hoc Advisory Committee of the National Academy of Sciences — National Research Council, Reviewing the Food and Drug Administration Research Program on Coal-tar dyes, June 1956, page 17.

Petitioner's brief (page 20) refers to the candy episode. This was not Red 32 but was FD&C Orange No. 1, a water soluble color not used in the coloring of oranges (R. 199-200) and the level of dye in the candy was seven hundredths of a percent (R. 211) and this is 175 times the highest concentration on the peel of the orange. The popcorn episode

was not in the evidence or hearings, happening after the hearings, (R. 155) and there was no evidence as to whether the illness was caused by rancid oil or other ingredients on the popcorn and it contained between 3000 and 9800 parts per million of color, between 750 and 2450 times as much as used on the outside of oranges. We feel that the Secretary erred in even considering occurrences outside the record in ruling upon petition to reopen and the offer of new evidence by Mr. Schnell.

FD&C Red 32 is harmless as used in the coloring of oranges. The record and analysis, as made by the Food and Drug Administration and evidenced by the following quotations, would seem to show there can be no dispute about this:

"There is, however, no evidence that in the amounts used and in the manner of use, in the coloring of citrus fruit, the product so colored is not safe for human consumption."

Statement of Honorable George P. Larrick, Commissioner of Food and Drugs, Department of Health, Education and Welfare. (R. 19)

Excepts from his statement made on hearings on H. R. 7732 are as follows:

"The tests of the toxicity of this color which have been made in the laboratories of the Food and Drug Administration were not designed to learn the effect of this color upon human beings when consumed by reason of its use on the skin of oranges and in the minute quantities that may thereby be ingested, but, rather, the tests were made to determine whether the color is harmless for use in foods generally.

".....

"While the scientific evidence so far available does not establish what the lowest safe dosage would be to test animals, neither does it establish a liklihood of injury to man from the use of this color on the exterior of oranges at the levels of use involved. This color has been in use for the coloring of oranges since the early 1930's. We have not found evidence, so far at least, that injury to consumers has resulted from the consumption of oranges so colored.

"Considering all of the information so far available — and bearing in mind particularly the minute amount of this dye likely to enter the human diet as a result of its use on oranges — we cannot say that its continued use on oranges, not intended for processing, would pose a hazard to the public health.

"... when as here there is no present evidence of injury to man from this particular use of the dye."

Hearings before a subcommittee of the Committee on Interstate and Foreign Commerce, House of Representatives, 84th Congress, Pages 17 and 18

The Senate committee in its consideration of H. R. 7732, which became Public Law 672 , 84th Congress, Chapter 530, 2d Session, 70 Stat 512, also construed the testimony of the Food and Drug Administration along the same lines, because, in its report reading in part as follows, it pointed out:

"...although the Administration testified before the committee that the scientific evidence so far available does not establish any likelihood of injury to man from use of this color on the exterior of oranges at the levels of use presently employed."

Sen. Rep. 2391, 84th Congress 2d Session, Pages 1, 2 and 3

A summary table on the concentration of dye on color-added oranges and its products appears in Exhibit 8, page 259 of the Record.

A summary made by the Food and Drug Administration of the amount used in feeding tests appears at page 160 of the Record. A comparative study of this in its relation to amounts used on citrus fruit and the quantity necessary to be used before affecting man is shown at pages 1, 12-13-14-15 of the Record.

The Petitioner in his brief referred to the fact that Dr. Gerwe is a chemist. Dr. Gerwe is considerably more than a chemist and his experience and education are shown in the Record at pages 19, 20 and 21. Regardless of this, this analysis is not just a study, it is more or less a recap of the actual data in Exhibit 8, R. 259, and R. 160. This shows that a person could drink a 5000-gallon tank full of orange juice every day without suffering any ill effects attributable to the presence of dye stuff. On the basis of a man's drinking 8 ounces of juice per day containing 0.0175 mg of color, this is only 1/80,000th of the intake which caused no affect when the dogs were fed for 5 years (R. 115) The rats were fed at a rate of 7550 times as much color as a man could get, if he ate 6 oranges, peel inclusive, per day. (R. 113) Thus it will be seen that the color was fed at an excessively high level having no relation to its use and there is no showing of any nature that it is likely to cause injury to man at normal levels of use or at the levels of use used in the coloring of oranges. In view of the fact that the color is on the outside, does not penetrate the rag and is not water-soluble, the amount likely to be taken into the human body is only on occasional instances and far less than the amount on the peeling itself.

B. The Statute, read as a whole and in the light of its

legislative and administrative history, intended that the uses and quantities of the coal-tar colors be taken in consideration in listing and certifying for use.

We disagree with the interpretation placed on the Statute by Petitioner. The construction of the word "harmless" has to be considered in a relative sense and not in an absolute sense. If we were to apply the per se doctrine of harmfulness and observe the Secretary's construction then vinegar, salt, pepper and many other articles of everyday diet could not even comply with the definition. The Lexington Mill and Elevator case (232 U. S. 399, 58 L. Ed. 658) shows that poisons in some greater amount are frequently present in potable water, bacon, ham, fruits and certain vegetables. The testimony on hearings on the Food, Drug and Cosmetic bill (Senate Hearings, S. 5, March 1935, p. 261) shows codliver oil contains arsenic, 1.4 to 5.1 parts per million, and shrimp and prawn, 30 parts per million (This is 7½ times the amount contained on the peel of colored oranges), and that fish, dandelions and lima beans contain arsenic.

Inasmuch as the discussion in subheadings B - 1 and B - 3 in Appellant's Brief, beginning on page 21 and page 27 of the brief, will overlap considerably and require the same authorities, we will discuss these together.

1. The terms of 402 (c) and 406 (b) do not require certified coal-tar colors to be wholly harmless for use in all foods, and (3) the legislative history and background of the statute did not intend to prohibit the listing or certification of coal-tar colors for any purpose or use when the only showing of toxicity was when fed at levels far greater than the normal levels of use and far greater than the particular use to which it was to be put.

Prior to the passage in 1906 of the Federal Food and Drug Act a series of appropriation act provisions beginning in 1900 authorized the Secretary of Agriculture to investigate the relationship of preservatives and coloring matters to health, and certain investigations of coal-tar colors were carried out under these amendments.

> Administrative Procedure and Practice in the Department of Agriculture under the Federal Food, Drug and Cosmetic Act of 1938, prepared under the direction of Mastin G. White, Solicitor (1940), p. 65.

The 1906 Act provided in Section 7:
"That for the purposes of this Act an article shall be deemed to be adulterated:...

"In the case of food:...

"Fifth: If it contains any added poisonous or other deleterious ingredient which may render such article injurious to health."

Shortly thereafter the commission was appointed draw up regulations. Although the word "harmless" was not used in the statute the regulations adopted by the Commission consistently used that word. For example, Regulation 12 provided:

"Only harmless colors may be used in food products." and the physiological experimentations leading up to the 1938 legislation treated harmlessness in relationship to the quantities and conditions of actual use rather than in an absolute sense.

The methodology is described as follows:

"The harmless nature of the color is appraised by a study of the results of (physiological) investigations. To be taken into consideration are the minimum lethal dose, as determined by the experiments, the chronic toxicity as demonstrated by damage to internal organs and growth rate, and the various dermal tests."

Herrick, Food Regulation and Compliance, v. 2, p. 998 (1947)

At the time of the passage of the Act Honorable Walter G. Campbell, the then Chief of the Food and Drug Administration of the United States Department of Agriculture, testified to the House Committee on Interstate and Foreign Commerce and his statement definitely shows that there was no claim of absolute purity and that the elements of quantity, use, etc. were to be considered, making reference to the then existing law and to the proposed measures:

"There are very few things, as an illustration, in which you will not find contaminating products in some small degree. With our industrial development, it is extremely difficult to acquire absolute purity, in the production of our food supply...

"Now, under the terms of the present law and under the terms of this measure as I have read it so far, action would be authorized in such cases only when the amount of that added deleterious ingredient was sufficient to injure health. There is a complete exclusion of added deleterious ingredients by this section, except where necessary in the production of the product or where unavoidable. In those instances the poison will be permitted or tolerated in amounts corresponding to the need of using the poison, or its unavoidability, in each particular food. The total of the amount so allocated will not be enough to jeopardize health."

Food and Drug Act — S. 5, Hearings, Committee on Interstate and Foreign Commerce, House of Representatives, 74th Congress, 1st Session, pp. 59-60, Dunn - Food, Drug and Cosmetics Act., Page 1251

Prior to the passage of the 1938 Act, coal-tar colors were not mentioned or treated specifically in the food and drug legislation, but they were certified under regulations of the Food and Drug Administration, and the legislative history shows that it was undoubtedly the Congressional intention to continue in effect a system of certification which had been followed almost from the beginning of the enforcement of the old Food and Drug law in order to make available to the food industry adequate supplies of colors of established safety and purity and that the Act was intended to codify the practices.

At that time there was in effect Regulation No. 13, entitled COLORS AND PRESERVATIVES, which read as follows:

"(a) Only harmless colors and harmless preservatives may be used in articles of food.

Regulations for Enforcement of Federal Food and Drug Act. (S.R.A.D.S. No. 1 issued Nov. 1930)

The intention is clearly shown by the testimony and the reports on the then pending bill. The following is testimony on one version of the Senate Bill:

"Mr. Campbell (at that time Chief, Food and Drug Administration) ...

"In Section 10 ... you will find, in the second paragraph of that secion...that the Secretary is authorized to make regulations, after notice and hearing, for the

certification of coal-tar colors which he finds to be harmless for use in food.

"The Chairman: That is not in the law now?

"Mr. Campbell: That is not in the law now.

"The Chairman: It is there by regulation.

"Mr. Campbell: By regulation we have actually done that. After the existing law became effective the then Bureau of Chemistry, in recognition of the impurities to be found in a great many coal-tar colors and the poisonous character of some of the colors themselves, issued regulations designed to assure the manufacturers and other purchasers that the colors used by them would be non-toxic and free from deleterious ingredients. These regulations established the practice of examining and certifying the purity and safety of coal-tar colors as a method for the protection of the public.

"It is desirable that it be continued. In this language we are asking for legislative confirmation of a practice which has existed since 1907.

Hearings before a Subcommittee of the Committee on Commerce, United States Senate, 73 Cong. 2d Sess. on S. 1944, Dec. 7, 1933 (U. S. Government Printing Office, 1943) pp. 28-29 Dunn 1065-66

Quotations from pertinent reports show the intent of Congress; the Senate report on the 1935 version of the bill

"As a matter of administrative practice in the Department of Agriculture, provision was made for the certification of coal-tar colors shortly after the enactment of the present law...This has resulted in an adequate

supply of harmless colors for all food uses and has operated to the satisfaction of the industry...Under Section 304(b) legislative sanction is given to the administrative practice of the Department in certifying colors."

Sen. Rep. No. 361, 74th Cong., 1st Sess (1935) Dunn, 243.

Similarly, the final report prior to the Conference Report states with respect to the sections:

"Subsection (b) of this section specifically authorizes the listing of harmless coal-tar colors for use in food and the certification of batches of the listed colors which are found to be sufficiently free from impurities to be safe. This continues in effect a system of certification which has been followed almost from the beginning of the enforcement of the old food and drug law in order to make available to the food manufacturing industries adequate supplies of colors of established safety and purity."

House Rep. No. 2139 (75th Cong., 3d Sess.) 1938 Dunn - 820

There is no indication in the legislative history that the language "harmless and suitable for use" was intended to mean harmless in an absolute sense. On the contrary, such an intention would have involved a repudiation of the standards developed and methods used in the administration of the prior Food and Drug legislation by the Department.

Finally, in the light of legislative history it is shown that a major purpose of the coal-tar color provision of the Act was to insure the continued availability of adequate supplies of colors for use by the Food Manufacturers' industry. The

hearings as heretofore cited clearly show that the Congress knew and the Department knew during the hearings and prior thereto that coal-tar colors were not harmless for all uses nor in all amounts. Therefore, legislation, one of the aims of which was to insure adequate supplies of such colors, could not be reasonably construed as meaning the word "harmless" in an absolute rather than a relative manner.

Not only the legislative history but the long time administrative construction shows that it was intended that the word "harmless" was to be construed in a relative rather than in an absolute manner. At the time of the certification of the coal-tar colors in 1939 shortly after the passage of the Act Dr. Calvary, then Chief of the Division of Pharmacology of the Food and Drug Administration, in testifying on certification hearings, (page 233 of the hearings) said:

"Q. Are there in your opinion any coal tar colors that are harmless and suitable for use in all kinds and classes of Foods, Drugs and Cosmetics.

"A. (Dr. Calvary), No, in my opinion there are no coal tar colors that are harmless and suitable for use in all kinds and classes of Foods, Drugs and Cosmetics..."

Later in the hearings he made the further statement: (page 243 of the hearings)

"Q. What do you mean by the terms that you have used, 'harmless and suitable for use'? The use to which the color is to be subjected?

"A. Yes, by harmless and suitable for use for the purposes indicated, we mean that in the concentrations that these substances are used for coloring

purposes, it is our opinion that no harm can come from them to the user when used in the concentrations for which they are designed"...

"Q. In considering the amount used, does the tinctorial property of these coal tar colors have some bearing on the amount used?

"A. Yes, the tinctorial properties of the coal tar colors is such that when they are used in foods, drugs and cosmetics they are used in relatively small percentages, and one takes that into consideration when one speaks of the toxicity of these substances assumed as harmless and suitable for use in drugs and cosmetics."...

"Q. Dr. Calvary, how do you arrive at percentage of color which should be allowed as harmless and suitable for use in foods, drugs and cosmetics?"

"A. We arrived at the conclusion that we have concerning the use of these from our conferences with the cosmetics, food and drugs manufacturers, and after learning from them what the percentages are which in most cases are a fraction of a per cent, we based our reasoning on that premise. The colors are not certified for use as colors to be consumed as colors. They are certified — at least we are permitting the listing of these for certification — on the basis of the fact that they will be used as we have been told they are being used at the present time, that is, in small percentages."...

Hearings U. S. D. A. FD & C. Docket No. 4 Feb. 7, 1939, pp. 233 and 243; Hearings USDA Docket FD&C 9, July 1939, Page 63

We respectfully call attention to the fact that the testi-

mony of Dr. Vos, hereinbefore quoted, upon which FD&C Red No. 32 was decertified, develops nothing new that was not developed in the testimony of Dr. Calvary just quoted and upon which the color was certified, and it will be seen that when the purpose of the Act was fresh in the minds of those who were to administer it it was recognized that concentrations and the purposes had to be considered in determining what was harmless.

The court decisions recognize that the terms must be relative and not absolute and that many food substances contain toxic materials.

In the case of Lexington Mill and Elevator Co. vs U. S., which was a case on adulteration of flour, the Court of Appeals reversed the District Court holding that the construction of the Trial Judge was strained and among other things said:

> "The trial Judge decided that if the added substance was qualitatively poisonous, although in fact added in such minute quantity as to be non-injurious to health, it still fell under the ban of the statute...There is no warrant in the statute for such strained construction. The object of the law was evidently:
>
> (1) To assure to the purchaser that the article was what it purported to be and
>
> (2) To safeguard the public health by prohibiting the inclusion of any foreign ingredients deleterious to health.
>
> (Citing Hall-Baker Grain Company vs. U. S., 198 Fed. 614)
>
> Lexington Mill and Elevator Co. vs. United States, 202 Fed. 615

Page 621 of the opinion is very enlightening and it shows the fact that poisons in some greater amounts are frequently present in potable water, bacon, ham, fruits and certain vegetables, etc.

This case went to the Supreme Court of the United States and in the opinion the Supreme Court upheld the decision of the Circuit Court of Appeals, and among other things, said:

"It is evident from the charge given and request refused that the trial Court regarded the addition to the flour of any poisonous ingredient as an offense within this statute, no matter how small the quantity and whether the flour might or might not injure the health of the consumer. At least such is the purpose of the part of the charge above given and if not correct it was clearly misleading, notwithstanding other parts of the charge seemed to recognize that in order to prove adulteration it is necessary to show that the flour would be injurious to health... (Page 661)

".....

"If it cannot by any possibility when the facts are reasonably considered, injure the health of any consumer, such flour, though having a small addition of poisonous or deleterious ingredients, may not be condemned under the act. This is the plain meaning of the words, and in our view needs no additional support by reference to reports and debates, although it may be said in passing that the meaning which we have given to the statute was well expressed by Mr. Heyburn, chairman of the committee having it in charge upon the floor of the Senate (Congressional Record, vol. 40, pt. 2, p. 1131):

" 'As to the term "poisonous", let me state that everything that contains poison is not poisonous. It depends

upon the quantity and the combination. A very large majority of the things consumed by the human family contain, under analysis, some kind of poison, but it depends upon the combination, the chemical relation which it bears to the body in which it exists as to whether or not it is dangerous to take into the human system' " (pp. 662 and 663)

Lexington Mill and Elevator Co., 232 U. S. 339, 58 Law Ed. 658

In the following case it was definitely established there was arsenic in the color, but notwithstanding this, the Court said:

"(2) We are not satisfied, however, that arsenic in such quantity as to be injurious to health was present. ...The government certifies color when arsenic is present, and when only slightly less than that found in the confiscated product.

"The evidence in the case does not present a disputed issue of fact, but rather a difference between chemists over the meaning of the words 'deleterious ingredient, injurious to health.' ...In other words, one would be required to drink 150,000 bottles of soda before he would have consumed a quantity of arsenic sufficient to equal the 'dose'.

"...The Congress has not assumed to define with absolute particularity what is or what is not injurious, and we cannot accept the testimony of the one witness who testified for the government to the effect that the word 'injurious' is an absolute term. Rather do we conclude upon the testimony before us that the arsenic present in the quantity disclosed was not injurious."

W. B. Wood Manufacturing Company vs. United

States, 286 Federal Reporter 84 Page 86 of the Opinion.

Just as the government wanted the word "poisonous" and the word "injurious" in the Lexington case to be construed in an absolute rather than a relative sense and in the Wood case wanted to have the word "injurious" so construed, so in this case does the Petitioner seek to have the words "harmless" and "harmful" construed in an absolute sense. The Court of Appeals of the Fifth Circuit followed the example of the U. S. Supreme Court in the Lexington Elevator case, supra, and did not agree with the Secretary as to his construction of the word "harmless". Neither did the Second Circuit agree with his construction of the word "harmless." The Lexington Elevator case was good law then and is still good law today. The use of the word "harmful" or the word "harmless" did not change the criteria. The word "injure" means to harm (Websters New Twentieth Century Dictionary, 2d E. page 944); to do harm to (Ballantine Law Dictionary, page 650.

The Court held that the small amount of arsenic in soda water was not injurious, that is without injury, so the minute amount of color on the rind of oranges would be harmless, that is without harm.

In the discussion of the point Petitioner, page 33 of the brief, refers to what was Section 3(e) of S. 2800. It will be observed, however, that this was primarily to do away with the labelling requirement. The citrus industry was already using the color they now use an it was considered has harmless and the Department, as pointed out by the Court of Appeals of the Seventh Circuit in the Wood case just cited, had been certifying a color as harmless when arsenic was present and considered this harmless because the regulations in effect promulgated by the Department, hereinbefore

set forth in this brief, used the word "harmless." The failure to include Section 3(e) in subsequent drafts of the bill did not mean a new interpretation of harmless, but merely meant abandonment of the proposed amendment regarding certain labeling requirements. The hearings clearly show this — Explanation of Congressman Wilcox, page 189, H. R. Hearings, Food, Drug & Cosmetic Bill 1935.

Petitioner's brief, page 23, makes the claim that one could use the color to achieve any tinctorial hue he desires and in any amount. This is incorrect. The Federal Food, Drug and Cosmetic Act prohibits the use of color to conceal inferiority and the Florida State statute prohibits dyes or colors that contain certain known poisons "or any other substances known to be injurious to health in excess of the amounts thereof permitted in certified food colors by regulations of the United States Department of Agriculture." (Section 601.75, Florida Citrus Code, F.S.A.) It, likewise, prohibits the colors that are "injurious to citrus fruit or to its keeping qualities or to result in the creation of an unstable and unsatisfactory color on the peel of the citrus fruit." (Sub-paragraph (4), Florida Citrus Code, F. S. A. 601.76) A color in excess of natural varietal colors is not allowed. The Florida implementing legislation passed as the result of conferences and cooperation with the Food and Drug Administration contemplates that the amount of color is to be considered and that certain ingredients are to be tolerated.

If the word "harmless" meant what the Food and Drug Administration claims it means there would be no need for the express distinction between the use of a color, under 406(b) for use in food, under 504 for use in drugs, and under 604 for use in cosmetics. If a color is harmless under the Food and Drug Administration interpretation it should

be suitable for use in any food, drug or cosmetic. There are many colors permitted for use in drugs and cosmetics that may not be used in food. The very fact that the problem of colors is dealt with in three separate sections of the Act is obvious proof that Congress recognized that some colors may be harmless under some circumstances of use but not under others. This is a clear recognition of the fact that safety must be related to conditions of use. Again the Secretary, when he lists a harmless color as an external D & C color, shows that he realizes that its use has to be considered and that it is different from an FD&C color. In our case the Secretary took colors off one list and put them on another, showing that the use must be considered.

2. The tolerance provision of Section 406(a) is applicable to coal-tar colors and the Secretary has power to certify for limited use and/or provide tolerances. (Petitioner's Brief 2)

The Secretary takes the position that he has no right to prescribe tolerances and the limitation of use. We disagree with him and feel that the whole history of the Act shows that he does have such right and the Court of Appeals of the Fifth Circuit so held.

From the statements made by the Secretary and F.D. and C officials the deleting of FD&C Red No. 32 was brought about by this erroneous construction of the law because the statements made in other parts of the brief recognize there is no likelihood of harm by reason of its use as such in the coloring of citrus fruit. In the certifying of Violet No. 1 the Department had previously recognized that they must tolerate because in certifying this color the Secretary said:

"The amount of color fed the animals in the tests referred to in finding No. 12 was far in excess of the

amount that any human might obtain as a result of food colored with F. D. and C. Violet No. 1."

Finding of Fact No. 13, 15 Fed. Reg. 3517 (June 7, 1950)

The Congress recognized that the color could not be harmless in an absolute sense and they recognized that limitations or tolerances would be in order. Otherwise, why should the Congress provide that the Administration shall promulgate regulations providing for the listing of coal-tar colors. It had been testified to at that time that all matter contained some deleterious matter and it was known that no coal-tar color was harmless and suitable for use in all kinds and classes of foods. Therefore, it would have been absurd and unreasonable to feel that Congress would have said "shall" when it knew no coal-tar color was suitable for all foods. Congress gave the Secretary broad power to make regulations.

The testimony of Mr. Campbell, sponsoring legislation and appearing before the committee for the Food and Drug Administration, pointed out at the hearing on the Food and Drug Bill (75th Congress, 1st Session, pages 358 and 359) that it authorized the establishment of tolerances for or the total prohibition of added poisons.

Section 402 with reference to adulteration on account of general ingredients and Section 402(c) with reference to adulteration by reason of containing a coal-tar color other than one from a batch which had been certified, both refer to Section 406, not 406(b) or 406(a), but 406, which shows that the Congress intended all of Section 406 to be construed together and it authorizes the granting of tolerances on coal-tar colors. Tolerances or certifying for specific uses are only methods of insuring that a color is harmless. If it

is without poison or deleterious substances then it can without question be certified. If there is some such substance then the tolerance provisions apply. This was recognized by Dr. Calvary, Chief of the Division of Pharmacology, Food and Drug Administration, as previously quoted, and was well pointed out by the Court of Appeals of the Fifth Circuit:

> "We see no reason for supposing Congress intended to permit the use of toxic substances, including toxic colors other than coal-tar products, in safe and harmless quantities and to prohibit the use of coal-tar colors in safe and harmless quantities." (R. 183)

This is good sense, particularly in view of the fact that coal-tar colors are not just colors that are capable of being made from coal tar chemicals but would include colors made from vegetable matters.

Tolerances are allowed for residual in apples, peaches, cherries and other fruit on which it is known that the outside peeling or rind will be eaten. Certainly we cannot assume that Congress, which specifically recognized the coloring of oranges, should require a higher standard and allow less flexibility for an oil soluble color that does not even penetrate the rag of the fruit as it is only placed on the outside on the rind which is not eaten and only in extreme instances and in infinitesimal amounts might get into the juice, so its undoubted purpose was to construe the word "harmless" in the light of the manner and quantity as used.

In addition to the mandatory provisions of the Act providing "The Secretary *shall* Promulgate regulations providing for the listing of coal-tar colors which are harmless and suitable for use in food." (Emphasis ours) (21 U. S.

C. A. 346a) Powers which could also authorize tolerances appear elsewhere in the Act.

Chapter VII, General Administrative Section, provides additional authority to promulgate regulations for the efficient enforcement of this Chapter, except as otherwise provided in the Section is vested in the Secretary. (21 U.S. C.A 371 (a)).

The Wood case, supra, points out under the old Act that the Secretary had provided tolerances for the inclusion of arsenic and other toxic extraneous materials in such colors. This was under the general powers prior to the passage of the 1938 Act. Although the Secretary now claims he has no authority to certify for a special use, yet in his Order, he took these colors off of one list and relisted them for external use in cosmetics, a restricted use. The Secretary has previously in Section 135.1 of the Regulations provided a restricted use by providing that the regulations for the certification of colors shall not authorize the certification of any such color for use in any article which is applied to the area of the eye. There was no specific statutory authorization for this limitation upon its use but it was upheld by our own Court of Appeals for the Fifth Circuit in Byrd vs. U. S., 154 F. 2d 62, wherein the Court said:

> "The statute contemplates that he shall not arbitrarily exercise his power, but shall act only upon a conscientious judgment derived from a consideration of the facts and conditions to which the regulation is to be applied."

Byrd vs. United States, 154 F. 2d 62 (5th Cir. 1946)

The Secretary had also previously listed a color for use for external application to egg shells. (20 F. R. 9554, 21

C.F.R. Par. 9.3(c)) This was pointed out by the Court of Appeals of the Fifth Circuit, page 184 of its opinion wherein the Court said "We merely observe that the Secretary restricted the use of a group of coal-tar colors to a single food and we feel he was empowered to do so."

3. The legislative history and background show that Congress intended that the purposes and uses should be considered in the listing of and certifying of coal-tar colors and that tolerances could be granted.

The entire record of the legislative hearings shows no intention to distinguish between coal-tar colors and other colors or food additives. Mrs. Baldwin, First Vice-president of the National League of Women Voters, testifying, page 39 of Senate Hearings, referred directly to Section 503 which was the coal-tar section for cosmetics and stated:

"... we do know that you can include in a cosmetic a certain amount of poison."

Senator Copeland, replying, among other things, said:

"Well, of course, that is covered by the general term that it should be deemed to be adulterated if it bears or contains any poisonous or deleterious substance which may render it injurious to health. So the Department itself would have to determine whether there was too much of this or that poison in the cosmetic, if there is any there."

Senate Hearings on S. 5 before Subcommittee of the Committee of Commerce, U.S. Senate, 74th Congress, 1st Sess., page 39.

In the colloquy between Chairman Copeland and Mr. Campbell in the Senate Hearings, among other things, the following was said:

The Chairman: "Here the quantity of harmful substances would be left to regulation by the department?"

Mr. Campbell: "That is right."

...

The Chairman: "I assume that you desire, as pictured in this bill, that the department, through some methods they shall work out, shall establish these various tolerances and then if you have them disputed in court, there would be one determination that a certain amount of arsenic would be the limit that can be used in a foodstuff. And, then, by that one decision, you would then establish that that was the legal limit of the use of arsenic; is that right?"

Other statements of Mr. Campbell bear out the same thing.

"We have tolerances now, merely administrative tolerances."

He also pointed out that the problems were so complex and so shifting "that they do not lend themselves effectively to rigid legislative expression" and that in figuring out who would determine what the physiological effect of the deleterious ingredients would be this "does not mean a cloistered group of individuals who do not know anything about marketing operations of food products, necessarily. . ." (Dunn 1059-60-61)

"We can deal in every individual case, under the language of the present law, with the particular product and prevent its being marketed if it contains any added deleterious ingredients which may be likely to injure health. We can take care of that situation in each individual case; fruit in one instance, eggs in another, and any other article of food." (Dunn 1062)

"We would determine the tolerances under the pro-

visions of this section exactly as we do the tolerances under the provisions of the existing law." (Dunn 1057)

"We propose this legislation with a full and complete understanding of the necessity for the protection of the public health not only but also of the protection of the economic interests of the growers."

". . . We recognize, at the same time, that tolerances must be established for fruit and vegetables, but should be restricted to amounts safe for consumption." (Dunn 1063)

Showing the discretion of the Secretary as to determining what is harmless, he also said:

". . . that the Secretary is authorized to make regulations, after notice and hearing, for the certification of coal-tar colors *which he finds to be harmless* for use in food (emphasis ours) Dunn 1065

On the next page he refers to safety, so there is nothing in the record to show a desire for discrimination against coal-tar colors in allowing tolerances and that the safety factor and not absolute purity was the goal. His statement, Dunn 1147, shows that this is merely asking for confirmation of an administrative practice that had prevailed for years in the certification of coal-tar colors. This administrative practice had been to allow certification even when at high levels it was harmful. At page 1153 his testimony shows "proper variations to expect under proper methods of control, . . ."

In a report to Representative Carl E. Mapes, House of Representatives, March 29, 1938, the then Secretary of Agriculture, H. A. Wallace, set forth in House Minority Report (Dunn 837)

"The bill delegates to the Secretary of Agriculture the

quasi-legislative power to ascertain the necessary technical facts and supply the details that will complete these definitions, thus effectuating the legislative will.

"The Secretary is entrusted with these powers in connection with sections 401, 403 (j), 404 (a), *406(a) and (b)*, 501 (b), 502 (d), 502 (f) exclusive of proviso, 502 (h), 504, and 604. These sections are extremely important. They relate to the identity and quality of food, to requirements with respect to special dietary food, to contaminated food, to poisonous substances in food, to coal-tar colors in food, drugs and cosmetics," etc.

It will be noted here that this report specifically construed the Act as allowing the Secretary to ascertain the necessary technical facts and supply the details and that it referred to both 406(a) and 406(b) and other regulatory sections as applying, among other things, to coal-tar colors in food.

David F. Cavers, Professor of Law, Duke University, who assisted in the drafting of the original Senate Bill, points out the difficulty of spelling out all the regulations in a single statute, Dunn 1180, and states:

"The facts which furnish the basis of the regulations are, of course, to be determined by the Secretary."

Instead of legislation proposing to get away from the Supreme Court interpretation the record shows it was intended to preserve the language of the Supreme Court decision. As Mr. Campbell pointed out in response to a question by Senator Clark, one of the purposes was "...and second, to preserve the use of the language which had already been considered by the Supreme Court." (Dunn 1140)

The Amended Senate Report, No. 152, 75th Congress, 1st Sess. (Dunn 687) points out that the bill must impose no

hardship which is unnecessary or unjustified in the public interest and will enable honest business to be carried on without interference except as is necessary to safeguard public health. There is no showing that the action of the Secretary in delisting this color was necessary in the public interest or to preserve the public health.

In the House, explaining wherein S. 5 differed from the previous law, knowing that coal-tar colors had been certified without specific legislative authority in the present law, Representative Chapman did not even make reference to the certification of coal-tar colors. His explanation of tolerances limiting the amount of added poison to the extent necessary to safeguard public health made no distinction between coal-tar colors and other colors or foods. (Dunn 577)

II

THERE IS A CLEAR SHOWING OF THE NECESSITY FOR USE OF THIS COLOR IN THE PRODUCTION OF ORANGES

We have previously discussed the applicability of Section 406 and 406(a) to coal-tar colors. The Schell brief deals in detail with the history and development of the coal-tar color and its necessity but the record shows that 59 per cent of the fruit has been colored since the certification of this color and in some areas and some packing houses 100 per cent. The Department of Agriculture has long recognized the necessity for the use of such a color and this will be developed more in detail in Sub-section B of this portion of the brief.

A. Section 406 was intended as a method for allowing tolerances and at the same time protect the public health.

'There was no flat prohibition against the use of a harmful substance when not harmful in the manner and quantity as used.

Section 402(a)(1) says:

"If the quantity of such substance in such food does not ordinarily render it injurious to health"

Section 402(a)(2) says:

"If it bears or contains any added poisonous or deleterious substance which is unsafe."

Petitioner argues that each food should be considered alone and we feel that each article can be considered alone. Just as Senator Copeland said "so much of this or that" a tolerance for one fruit or vegetable can be one thing and another amount for another fruit or vegetable, and the Secretary knowing how much color is being certified can limit the amount by knowing the entire possible intake from all sources.

FD&C Red No. 32 was being used prior to the passage of the Act. Shortly after the passage of the Act hearings were held and it was certified as safe for use in foods and has been in use for more than 20 years. At the time of filing of these proceedings more than 250 million boxes of oranges had been colored without complaint or any injury to man. For the seasons 1945-46 through 1956-57 68.2 per cent of all oranges shipped out of the State of Florida used this color. The color-added range from season to season ran from 60 per cent of oranges shipped to 76.3 per cent of oranges shipped. (Annual Report, Citrus Inspection Bureau, Florida Department of Agriculture, 1958) The hearings on H. R. 7732, supra, show a table of shipments for certain periods and show that 100 per cent of oranges in Texas in certain seasons were color added.

The Department of Agriculture and the industry have for years recognized the necessity of coloring oranges in order to market them and certainly the production of a fruit does not end when it is on the trees.

B. FD&C Red No. 32 is the only certified color used in the coloring of oranges. Its use is required in the production of oranges and cannot be avoided by good manufacturing practice.

Petitioner's brief states that the Secretary was not at all concerned with the question whether Red 32 is required in the production of oranges and then seeks to argue that the record does not show that it is required in the production of oranges. We must again call attention to the fact that all necessary elements for the certification had been established in the 1939 hearings. The Secretary in the hearings on which he decertified the three colors was considering only one point, whether at any levels the colors were harmful. The record shows, as has been discussed elsewhere, that it was harmless as used in the coloring of oranges and there is no showing that the color was harmful in any normal levels of use.

Elsewhere in this brief we have pointed out that this is the only color certified that is used in the coloring of oranges and that it is not used for any other purpose. The record and scientific publications clearly show that in order to market oranges in fresh form it is necessary to color. The U. S. Department of Agriculture, which for a long period of time had within it the Food and Drug Administration, in several of its technical and official publications so stated:

"It is well known that citrus fruits grown under certain climatic and cultural conditions may be mature and highly desirable for food while the skin of the fruit is

still green in color . . . In general, when it reaches full color on the trees the fruit in this region is characterized by a low acidity, with a comparatively high sugar content, and the overripe fruit is inclined to be insipid in flavor. It is important then, if this fruit is to be furnished to the consuming public in its most desirable condition for food, that it be harvested before it becomes yellow on the trees . . . It is evident, then that some method of treating this fruit so that it would assume a rich orange yellow color early in the season, when it is most desirable for food, would be of benefit to the industry and to the consuming public alike."

U. S. D. A. Bulletin No. 1159, August 1923

"Some of the early fall varieties of oranges and grapefruit ripen while the fruit is still green in color . . . There is, therefore, no definite relation between flavor or maturity and the color of the fruit while on the tree. However, there is a very significant relation between the color of the fruit offered for sale and the price it will bring, and citrus fruit producers have always faced the problem of making the color of ripe fruit match its flavor."

U. S. D. A. The Year Book for 1932, pp. 134-137

"It is obvious, then, that treating fruit which is physiologically mature or has reached a stage in its development at which it has high dessert quality, so that it assumes a color or appearance pleasing to the eye and has a higher decorative value, is a legitimate practice in marketing and one which should be encouraged."

U. S. D. A. Bulletin 1367, May 1926, 167.

The Senate Report on H. R. 7732, pages 1 and 2 of the Report, recognizes the economic necessity and the lack of

likelihood to cause injury and uses the following wording:

"This practice has become an economic necessity for a major segment of the orange industry, since large quantities of oranges grown in Florida and Texas would meet with strong consumer resistance if they are not artificially colored.

...

"The need for this legislation arises because the only coal-tar color suitable for coloring oranges (F. D. & C. Red 32) has been stricken from the approved list by the Food and Drug Administration. The Administration, after public hearing, concluded that this particular coal-tar color was not harmless but was toxic, and that under the present law the Administration could not list this color as 'harmless and suitable for use in food' although the Administration testified before the committee that the scientific evidence so far available does not establish any likelihood of injury to man from use of this color on the exterior of oranges at the levels of use presently employed."

Sen. Rep. 2391, 84th Congress, 2d Session, Pages 1, 2 and 3

The House Report contained substantially the same matter. The Court of Appeals for the Fifth Circuit also pointed this out in its opinion (R 182) and pointed out that it is as important that a food be marketable as that it be palatable.

The principal purpose of producing any agricultural commodity on a large scale is for marketing We have passed the time when the grower merely raises for his own consumption and the words "production thereof and good manufacturing practice" embrace those things that are necessary to get the product ready to ship.

The petitioner refers to the use of poisonous artificial sweeteners. This is a matter in which the artificial sweeteners are included in the food itself and where other sweeteners can be used in the foods and is a different problem entirely from the coloring of the outside of oranges where only a minute quantity at most can get into the orange itself. In the brief it refers a number of times to a list of colors available for restricted use. We submit that this is one of the errors made in his original ruling in taking the position that he could not certify for a restricted use. The Secretary would limit the term "required in production" to the substance required in growing the fruit, not post-harvest treatment.

Petitioner seeks to limit the meaning of "required in production" and cited in support thereof (Brief, p. 43) the case of Armour & Co. vs. Wantock, 323 U. S. 126, 129-130, but we feel the construction of this case is favorable to our side. The Court said:

> "So too, no hard and fast rule may be transposed from one industry to another to say what is necessary in 'the production of goods.' ". (Headnote 3)

This case involved the question of whether a watchman was under the Wage and Hour Law and whether he was engaged in the production of goods for commerce and the case held he was. The Court also used rather interesting wording:

> "Whatever terminology is used the criteria is necessarily one of degree and must be so defined."

This case cited the case of Santa Cruz Packing Co. vs. N.L.R.B. (303 U. S. 453, 467; 82 L. Ed. 954, 960; 58 S. Ct. 656) and also pointed out that the restrictive words like indis-

pensable would not have the automatic significance sought to be given them by Petitioner.

Under the Fair Labor Standards Act there are a large number of cases dealing with production and the production of goods for commerce and it has been held repeatedly that grading, packing and selling were production of goods for commerce. (Walling vs. McCracken County Peach Association, D. C. Kentucky 50, Fed. Sup. 900-904; Sikes vs. Lochmann, 132 P. 2d 620-624; 156 Kan 223) If the packing house employees are an essential part of production the coloring of oranges is a part of production because packing and processing are a part of production and this is a portion of the processing.

The Court of Appeals of the Fifth Circuit in its opinion (R. 179) pointed out that they were reviewing the order with respect to the coal-tar color Red 32 as used in the coloring of the skins of oranges, that they are not confronted with the broad questions that were before the Second Circuit in the Certified Color Industry case. It reversed the Secretary only in part and pointed out the powers of the Secretary so a construction of the opinion should not give rise to the fears expressed on page 44 of Petitioner's brief.

The Secretary takes the position a substance harmful at any level or any use was banned without regard to whether the added substance might or might not render the treated food injurious. This is contrary to the entire concept of the Food, Drug and Cosmetic Act. The two purposes of the Act were to protect the public health and to prevent deceit. Neither of these purposes is served by denying the use of a color harmless as used and in such manner that it would be impossible for a human being to ingest enough color from eating oranges to reach any level at which he would be harmed. The Department of Agriculture and the Congress

of the United States have approved the use of coloring and have declared it an economic necessity in the coloring of oranges. The Secretary takes the position that this decision will have far reaching consequences beyond the question of Red 32 for oranges. This statement of the Secretary was made prior to the passage of Public Law 85-929 and this decision will now have no effect upon the other food additives. Congress has now spoken again. If this be a reversal of the national food policy which has been followed for years Congress has itself entered into such reversal, but the policy on oranges is the policy that has been followed for years.

III

THE COURT BELOW DID NOT MAKE ITS OWN FINDINGS THAT COLORING OF ORANGES IS REQUIRED FOR PRODUCTION AND CASTING ON THE SECRETARY THE BURDEN TO SHOW THAT SAFE TOLERANCES CAN BE ESTABLISHED. THE COURT FOLLOWED THE CLEARLY ESTABLISHED FACTS AND THE LAW

The point made by the Secretary, pp. 44-45 of his brief and elsewhere, referring to the use of similar substances in other foods, is now made obsolete by reason of the passage of Public Law 85-929, 72 Stat. 1784.

The Court of Appeals did not presume that proper tolerances could be established, it left the matter to the Secretary as is clearly shown by the following quotation from the opinion:

> "... and if he finds that such use is so required, then to determine the quantity, if any, that can be tolerated as safe, and by regulation to limit the quantity to such extent as he finds necessary for the protection of public health...."

(R. 183) and in the concluding sentence of the opinion. (R. 187)

A. Neither did the Court establish a tolerance but determined that the Secretary could provide a tolerance for coal-tar colors. The record shows that only four parts per million of color is used on oranges, far less than the intake of many substances in normal foods; that on the basis of the amounts fed to animals it would be impossible with this small percentage of color for a human being even to intake enough to be harmful because he would never have the capacity to eat that many oranges or drink that much juice. The quantity on the oranges and in the juice appears in the record.

The reason we have quoted the Department and Commissioner Larrick's statements before the committee is that this is their own evaluation of what they had found, showing that the amount to be ingested was minute, that it had not been shown that it would be harmful and that there was little likelihood of its being harmful.

The Petitioner takes the position that the facts needed to establish safe tolerances do not exist; the record does show the amount used on oranges; the Allmark study shows for FD&C Red 32 a point of no-effect far in excess of the amount used in the coloring of oranges and the Commissioner had the results of his own studies, but, as we have pointed out before, the Court did not say this was a tolerance. It merely provided, among other things, that the Secretary could establish a tolerance and he can take more testimony if he desires.

The comment is made by the Secretary on the statement of Dr. Gerwe. Dr. Gerwe is more than just a chemist as will be seen by the report of his experience, supra, and he ana-

lyzed the evidence in its relation to man. The Secretary had felt that if a coal-tar color would harm at any level he could not certify it and must take it off of the certified list, that he had no right to limit the level of use and that he had no right to certify for particular use, therefore the tests were made at abnormally high levels to determine if the colors were harmful at any level. The Court pointed out that "harmless" should be construed in a relative sense, that he could limit the amount and that he could certify for particular purposes, but clearly left the determination of the necessity, the quantity and the use to the Secretary.

Answering the Note No. 21 of the Secretary's Brief, pp. 48-49, this comment does not take into consideration exports and that no coloring process is 100 per cent efficient, that considerably more color is used than goes into the rind of the orange, that considerable of the residue is rinsed off and discarded, that leaves, twigs, etc. get into the coloring bath and that these baths are discarded with substantial amounts of color still in them.

B. The Court of Appeals did not assume the safety of Red 32. It took the Secretary and the Food and Drug Administration's own interpretation of what the evidence showed. The record before the Court showed that it was harmless as used. In this case the Secretary was the proponent, the Secretary was seeking to take from the certified list a color that had been used for the coloring of oranges for more than 20 years, was in use prior to the passage of the Food, Drug and Cosmetic Act, and, after hearings in which Dr. Calvary had testified that no coal-tar color was harmless for all uses, had been certified in 1939 "as harmless and suitable for use in foods".

The Administrative Procedure Act, which is applicable to the Secretary, hereinbefore quoted, provides that the pro-

ponent of a rule of order shall have the burden of proof. The Food, Drug and Cosmetic Act provided he should base his order only on substantial evidence of record at the hearing. There was a lack of substantial evidence warranting the color being taken off the list. The evidence, as quoted in other parts of this brief, was about the some on which the color had been certified.

The Secretary, Brief page 51, quotes the Supreme Court to the effect that the Act does not contemplate that the Court should substitute their own judgment for that of the Administrator. The debates and records clearly show the strong intent for Court review of these orders as a safeguard against erroneous action. The Supreme Court points out that certain interpretations of the statutes are not the substitution of the will of the Judge for that of the legislature.

> "It is a familiar rule that a thing may be within the letter of the statute and yet not within the statute, because not within the spirit nor within the intention of its makers."
>
> "'This is not the substitution of the will of the Judge for that of the Legislator, for frequently words of a general meaning are used in a statute, words broad enough to include an act in question, and yet a consideration of the whole legislation or the circumstances surrounding its enactment, or the absurd results which follow from giving such broad meaning to the words, makes it unreasonable to believe that the Legislator intended to include the particular Act. (Holy Trinity Church vs. United States, 145 U. S. 457, 459, 12 Supreme Court 511, 512, 36 Law Ed. 226)"

The Supreme Court of the United States in concluding the case just above recited used this language:

"It is the duty of the Courts under those circumstances to say that however broad the language of the statute may be, the act, although within the letter, is not within the intention of the legislature, and cannot come within the statute."

In a Food and Drug case the Circuit Court of Appeals in the 2nd Circuit used this wording as to the interpretation of the then Food and Drug Act:

"The general language should not be so construed to ruin a legitimate business and yet remedy none of the evils the statute was designed to remove."

French Silver Dragee Co. v. United States 179 Federal 824

The Court of Appeals of the Fifth Circuit in its decision points out (R. 178):

"... Results which are incongruous or absurd are to be avoided. Where a particular construction of a statute will occasion great inconvenience or produce inequality and injustice, that view is to be avoided if another and more reasonable interpretation is present in the statute. In the construction of a legislative measure, statutes in pari materia, amendatory acts, and their legislative history may be examined. These rules are the primary guides to our solution of the problem before us."

and the opinion itself (R. 178) cites the various cases of the Supreme Court of the United States which they consider in reaching this conclusion.

What the Supreme Court has said and the Fifth Circuit has said was also said about this bill in the Senate Report and by President Franklin D. Roosevelt in his message to the Congress included in the House Report.

"... and, third, it must impose on honest industrial enterprise no hardship which is unnecessary or unjustified in the public interest."

Dunn—687, Amended Report, Senate, Rep. No. 152 75th Congress, 1st Sess.

"No honest enterpriser need fear that because of the passage of such a measure he will be unfairly treated. He would be asked to do no more than he now holds himself out to do..."

Dunn—267, House Report 74th Congress, 2d Sess., Message from President Franklin D. Roosevelt, March 22, 1935.

IV

RECENT LEGISLATION

While this brief was being prepared the Congress passed "The Food Additives Amendment of 1958" The definition of food additives appears in Sub-section (s) of Section 2 and contains among other things the following wording:

"The term 'food additive' means any substance the intended use of which results or may reasonably be expected to result, directly or indirectly, in its becoming a component or otherwise affecting the characteristics of any food (including any substance intended for use in producing, manufacturing, packing, processing, preparing, treating, packaging, transporting, or holding food;" etc.

Public Law 85-929, Sec. 2(s), H. R. 13254, 85th Congress, 72 Stat 1784.

This legislation certainly puts at rest all references in

the Petitioner's brief as to the effect of the Court decision on sweeteners, oleomargarine and other substances added in other foods. This legislation provides that the Secretary can establish a regulation, prescribe the conditions under which such additive may be safely used. Both the Senate Report and the House Report explain the concept of safety as follows:

> "The concept of safety used in this legislation involves the question of whether a substance is hazardous to the health of man or animal. Safety requires proof of a reasonable certainty that no harm will result from the proposed use of an additive. It does not—and cannot—require proof beyond any possible doubt that no harm will result under any conceivable circumstance.
>
> "This was emphasized particularly by the scientific panel which testified before the subcommittee. The scientists pointed out that it is impossible in the present state of scientific knowledge to establish with complete certainty the absolute harmlessness of any chemical substance."
>
> House Report 2284, pp. 4, 5, 85th Congress, 2d Sess.
>
> Senate Report 2422, p. 6, 85th Congress, 2d Sess.

It will be noted here that as the Supreme Court had pointed out in the Lexington Mill case, supra, and the Woods case, supra, and as the Court of Appeals for the Fifth Circuit pointed out in this case, the Congress pointed out clearly the impossibility with complete certainty to establish absolute harmlessness of any chemical substances and said on page 2 of the Senate Report:

> "Conscious of the fact that any substance or, for that matter, any particular food known to be good for the

> health of human beings can be deleterious to the health of an individual who insists on consuming inordinate amounts of it, . . ."

and goes on to say that to eat a pound of salt or drink four gallons of pure water in an hour would be harmful and explains that the testimony would be to determine whether or not a particular additive used in a specific percentage of relationship to the volume of the product to which it might be added should be that of reasonable certainty in the minds of competent scientists that the additive is not harmful to man or animal. Thus, it will be seen that Congress did not use "harmful" in an absolute sense. The previous departmental canon of construction of "malum in uno, malum in omnibus" is erroneous. Page 3 of the Senate report uses the expression "'safe for humans and animals when used in or within certain quantitative limits." On page 4 of the same Report—"An additive may be shown to be safe either by means of scientific procedures (including a review of existing scientific literature) or, in the case of substances in use prior to January 1, 1958, also by means of experience based on common use in food. And on page 5 states:

> "The principal examples of both intentional and incidental additives are substances intended for use in producing, manufacturing, packing, processing, preparing, treating, packaging, transporting, or holding food."

Under the Secretary's present construction, even though the research referred to in H. R. 7732 has been completed and a color with a far greater safety factor than FD&C Red No. 32 has resulted therefrom, this new color could not be certified. A continuation of this construction would be to maintain in the coal-tar area the same unworkable and obsolete principle of utter exclusion that Congress has finally expunged. Affirmation by this Honorable Court of the Fifth

Circuit position is not going to cause any deep-seated or radical change since these changes have already been required by legislation. It would be absurd to say it can be allowed inside the orange and not on the outside and it was pointed out by the Court of the Fifth Circuit even before this new legislation:

> "Such a construction would be an unwarranted discrimination, not so much against the coal-tar color and the manufacturers of it, but against that important segment of the orange producers who are economically dependent upon it. The construction of the Secretary results, or may result, in inequality and injustice. There is, we think, a more reasonable interpretation in the Act." (R. 181)
>
> Florida Citrus Exchange et al vs. M. B. Folsom, 246 Fed. 2d 850

This reasonable construction authorized the Secretary to construe "harmless", taking into consideration the use and quantity, and to set tolerances or safety factors at a level that would not endanger the public health or to certify for limited use.

CONCLUSION

For the foregoing reasons we respectfully submit that the judgment of the Court below should be affirmed.

Respectfully submitted.

J. HARDIN PETERSON
P. O. Box 111
Lakeland, Florida
Attorney for all Respondents other than Frank R. Schell

J. HARDIN PETERSON, JR.
of Counsel

PROOF OF SERVICE

I, James Hardin Peterson, attorney for Florida Citrus Exchange and all other Respondents except Frank R. Schell, and a member of the bar of the Supreme Court of the United States, hereby certify that on the ..... day of October, 1958 I mailed Air Mail, postage prepaid, five copies of the attached brief to:

HONORABLE J. LEE RANKIN
Solicitor General
Department of Justice
Washington 25, D. C.

HONORABLE WILLIAM W. GOODRICH
Department of Health, Education and Welfare
Washington 25, D. C.

.....

J. HARDIN PETERSON
P. O. Box 111
Lakeland, Florida
Attorney for Respondents
other than Frank R. Schell

IN THE
SUPREME COURT OF THE UNITED STATES

October Term, 1958

No. 27

MARION B. FOLSOM, SECRETARY OF HEALTH, EDUCATION AND WELFARE
Petitioner

versus

FLORIDA CITRUS EXCHANGE, FRANK R. SCHELL, ET AL
Respondents

REQUEST FOR ORAL ARGUMENT

The Respondents, other than Frank R. Schell, by their undersigned attorney, respectfully request oral argument.

J. HARDIN PETERSON
P. O. Box 111
Lakeland, Florida
Attorney for Respondents
other than Frank R. Schell

J. HARDIN PETERSON, JR.
of Counsel